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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|---------------------------|---------------------|------------------|
| 10/578,899 | 01/31/2007 | Michal Eisenbach-Schwartz | EIS-SCHWARTZ32A | 3343 |
| 1444 | 7590 | 12/08/2010 | EXAMINER | |
| Browdy and Neimark, PLLC 1625 K Street, N.W. Suite 1100 Washington, DC 20006 | | | KIM, TAEYOON | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |
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| | | | 12/08/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/578,899 | Applicant(s) EISENBACH-SCHWARTZ ET AL. | |
| | Examiner Taeyoon Kim | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,26,28,31,32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 28 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,26,32 and 34-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>9/24/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment and response filed on 9/24/2010 has been received and entered into the case.

Claims 1-23, 25, 27, 29, 30 and 33 are canceled, claims 28 and 31 are withdrawn from consideration as being drawn to non-elected subject matter, and claims 24, 26, 32 and 34-37 have been considered on the merits. All arguments have been fully considered.

The previous claim rejection under 35 U.S.C. § 112 has been withdrawn.

A new claim rejection under 35 U.S.C. § 112 is made to claims 34-36.

It is noted that the previously withdrawn rejection under 35 U.S.C. § 102 has been reinstated. The Examiner has indicated that the reason for the withdrawn of 102 rejection based on Eisenbach-Schwartz et al. (US 2002/0037848) was due to the enablement argument presented in the previous amendment on 4/8/2010. However, considering the current argument against the enablement rejection, and the inventor of the cited reference ('848 application) is the same as the inventor of the current application, it is considered that the disclosure of the '848 application enables a person of ordinary skill in the art at the time of the reference since the method disclosed in the '848 application is identical, and based on the current application, it is concluded that the method of '848 application would inherently produce the same results as the currently claimed invention. In addition, the copending application (2003/0004099; now US Pat. 6844314) to the '848 application by the same inventor has been patented, indicating that the disclosure of the both '099 and '848 application are enabling. Therefore, the claim rejection under 35 U.S.C. § 102(b) based on Eisenbach-Schwartz et al. (US 2002/0037848) has been reinstated.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a neurodegeneration caused by glutamate toxicity including Huntington's disease, does not reasonably provide enablement for any other neurodegenerative disease particularly prion disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

The instant claims are interpreted as a method for treatment of a patient suffering from a neurodegenerative disease or a patient suffering from a disorder selected from the group consisting of HD and AD.

Considering the patient suffering from a neurodegenerative disease, the current claims can be construed as a method for treatment of a patient suffering from ANY neurodegenerative disease. The specification discloses that prion disease, which is known as a neurodegenerative disease, is excluded from the current invention and thus it is not within the scope of the current invention (see p.1 of the specification). However, the current claims broadly disclose any neurodegenerative disease to encompass prion disease.

Applicant is advised to amend the claims commensurate with the scope of the current invention. For example, the instant claims can be amended to limit the neurodegenerative disease to HD and/or AD.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 24, 26, 32 and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Eisenbach-Schwartz et al. (US 2002/0037848; of record).

Eisenbach-Schwartz et al. teach a method of administering or immunizing copolymer I (or Cop I) to a patient suffering neurodegenerative diseases such as Huntington's disease, and reducing or protecting glutamate toxicity (see entire document; esp. Abstract; par. 26, 97 and 116).

Thus, the reference anticipates the claimed subject matter.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651